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EXAMINER	
VIVLEMORE, TRACY ANN	
ART UNIT	**PAPER NUMBER**
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,446	INANA ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-14 and 27-29, drawn to a method of delaying or reversing a retinal or choridal degenerative disease in a subject using an agent that modulates expression or activity of a AMDP-related or phagocytosis related gene wherein the agent is a ribozyme, classifiable in class 514, subclass 44. Election of this group requires a further election of an AMDP-related or phagocytosis related gene by SEQ ID NO from claim 2 as set forth below. Election of this group requires a species election as set forth below.

II. Claims 2-14 and 27-29, drawn to a method of delaying or reversing a retinal or choridal degenerative disease in a subject using an agent that modulates expression or activity of a AMDP-related or phagocytosis related gene wherein the agent is an antisense RNA, classifiable in class 514, subclass 44. Election of this group requires a further election of an AMDP-related or phagocytosis related gene by SEQ ID NO from claim 2 as set forth below. Election of this group requires a species election as set forth below.

III. Claims 2-14 and 27-29, drawn to a method of delaying or reversing a retinal or choridal degenerative disease in a subject using an agent that

modulates expression or activity of a AMDP-related or phagocytosis related gene wherein the agent is an interfering RNA molecule, classifiable in class 514, subclass 44. Election of this group requires a further election of an AMDP-related or phagocytosis related gene from claim 2 as set forth below. Election of this group requires a further election of an AMDP-related or phagocytosis related gene by SEQ ID NO from claim 2 as set forth below. Election of this group requires a species election as set forth below.

IV. Claims 2-14, drawn to a method of delaying or reversing a retinal or choridal degenerative disease in a subject using an agent that modulates expression or activity of a AMDP-related or phagocytosis related gene wherein the agent is a triple helix forming molecule, classifiable in class 514, subclass 44. Election of this group requires a further election of an AMDP-related or phagocytosis related gene by SEQ ID NO from claim 2 as set forth below. Election of this group requires a species election as set forth below.

V. Claims 2-13 and 15-17, drawn to a method of delaying or reversing a retinal or choridal degenerative disease in a subject using an agent that modulates expression or activity of a AMDP-related or phagocytosis related gene wherein the agent is an antibody, classifiable in class 530, subclass 387.1. Election of this group requires a further election of an AMDP-related or phagocytosis related gene by SEQ ID NO from claim 2

as set forth below. Election of this group requires a species election as set forth below.

VI. Claims 2-13 and 18, drawn to a method of delaying or reversing a retinal or choridal degenerative disease in a subject using an agent that modulates expression or activity of a AMDP-related or phagocytosis related gene wherein the agent is a small molecule, classifiable in class 424, subclass 93.1. Election of this group requires a further election of an AMDP-related or phagocytosis related gene by SEQ ID NO from claim 2 as set forth below. Election of this group requires a species election as set forth below.

VII. Claims 19-26, drawn to a method of determining risk of a subject of developing a retinal or choridal degenerative disease or condition, classifiable in class 435, subclass 6. Election of this group requires a further election of a single nucleotide sequence and an amplimer pair as set forth below.

VIII. Claim 30, drawn to a method of treating a retinal or choridal degenerative disease or condition using a vector that encodes a wild type or polymorphic variant of an AMDP-related or phagocytosis related protein, classifiable in class 435, subclass 320.1.

IX. Claims 31 and 32, drawn to a composition comprising an agent that blocks the expression or activity of an AMDP-related or phagocytosis-related protein, classifiable in class 536, subclass 24.5.

X. Claims 33 and 34, drawn to a composition comprising a vector that encodes a wild type or polymorphic form of an AMDP-related or phagocytosis-related protein, classifiable in class 435, subclass 320.

XI. Claims 35-37 and 44, drawn to a nonhuman transgenic animal that overexpresses a protein, classifiable in class 800, subclass 8. Election of this group requires a further election of a protein that is overexpressed as set forth below. Election of this group requires a species election as set forth below.

XII. Claims 38-39, drawn to a nonhuman transgenic animal that expresses a polymorphic variant of an AMDP-related or phagocytosis-related protein, classifiable in class 800, subclass 8.

XIII. Claims 40-43, drawn to a nonhuman transgenic animal that expresses two polymorphic variant proteins, classifiable in class 800, subclass 8. Election of this group requires a species election as set forth below.

XIV. Claim 45, drawn to an isolated nucleic acid of comprising SEQ ID NO: 1, classifiable in class 536, subclass 23.1.

XV. Claim 46, drawn to an isolated nucleic acid of comprising SEQ ID NO: 4, classifiable in class 536, subclass 23.1.

XVI. Claim 47, drawn to an isolated nucleic acid of comprising SEQ ID NO: 5, classifiable in class 536, subclass 23.1.

XVII. Claim 48, drawn to an isolated nucleic acid of comprising SEQ ID NO: 12, classifiable in class 536, subclass 23.1.

XVIII. Claim 49, drawn to an isolated nucleic acid of comprising SEQ ID NO: 17, classifiable in class 536, subclass 23.1.

XIX. Claims 50-52, drawn to a gene array, classifiable in class 435, subclass 6. Election of this group requires a further election of sequence encoding a cDNA as set forth below. Election of this group requires a species election as set forth below.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Inventions I-IV are directed to methods of using nucleic acid agents, invention V, which uses an antibody and invention VI, which uses a small molecule inhibitor. The inventions that use nucleic acids to perform the method have differing modes of operation from each other. Invention I uses a ribozyme, which acts by cleaving a target molecule; invention II uses an antisense RNA, which acts by activating RNAse H; invention III uses an interfering RNA molecule, which acts by activating the RISC complex and invention IV uses a triple helix forming molecule, which acts by binding DNA and blocking transcription.

2. Furthermore, examining any of inventions I-VI together would impose a serious search burden. In the instant case, prior art searches of methods of delaying or

reversing a retinal or choridal degenerative disease in a subject using an agent that modulates expression or activity of a AMDP-related or phagocytosis related gene wherein the agent is a ribozyme are not coextensive with prior art searches of methods of delaying or reversing a retinal or choridal degenerative disease in a subject using an agent that modulates expression or activity of a AMDP-related or phagocytosis related gene wherein the agent is any other type of molecule. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-VI together.

3. Claim 1 link(s) inventions I-VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is

withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Inventions I-VI are unrelated to invention VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions I-VI is to delay or reverse a retinal or choridal degenerative disease or condition while the function of invention VII is to determine the risk of a subject developing a retinal or choridal degenerative disease or condition.

5. Furthermore, examining any of inventions I-VI together with invention VII would impose a serious search burden. In the instant case, prior art searches of methods of delaying or reversing a retinal or choridal degenerative disease in a subject are not coextensive with prior art searches of methods of determining risk of a subject developing a retinal or choridal degenerative disease. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-VI together with invention VII.

6. Inventions I-VI are unrelated to invention VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions I-VI is to delay or reverse a retinal or choridal degenerative disease or condition while the function of invention VIII is to treat a retinal or choridal degenerative disease or condition using a vector that encodes a wild-type or polymorphic variant of an AMDP-related or phagocytosis-related protein.

7. Furthermore, examining any of inventions I-VI together with invention VIII would impose a serious search burden. In the instant case, prior art searches of methods of delaying or reversing a retinal or choridal degenerative disease in a subject are not coextensive with prior art searches of methods of treating a retinal or choridal degenerative disease or condition using a vector that encodes a wild-type or polymorphic variant of an AMDP-related or phagocytosis-related protein. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-VI together with invention VIII.

8. Inventions I-VI and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the process could be performed with a materially different product, for example, a retinal or choridal degenerative disease could be treated with a laser using laser photocoagulation.

9. Furthermore, examining any of inventions I-VI together with invention IX would impose a serious search burden. In the instant case, prior art searches of methods of delaying or reversing a retinal or choridal degenerative disease in a subject using an agent that can either decrease or increase expression or activity of a gene are not coextensive with prior art searches of compositions of agents that only decrease activity of a gene. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-VI together with invention IX.

10. Inventions I-VI are unrelated to invention X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions I-VI is to delay or reverse a retinal or choridal degenerative disease or condition while the function of invention X is to encode a wild-type or polymorphic form of an AMDP-related or phagocytosis-related protein.

11. Furthermore, examining any of inventions I-VI together with invention X would impose a serious search burden. In the instant case, prior art searches of methods of delaying or reversing a retinal or choridal degenerative disease in a subject are not coextensive with prior art searches of vectors that encode a wild-type or polymorphic variant of an AMDP-related or phagocytosis-related protein. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-VI together with invention X.

12. Inventions XI-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of the animal of invention XI is to overexpress a protein, the function of the animal of invention XII is to express a polymorphic variant of an AMDP-related or phagocytosis related protein and the function of the animal of invention XIII is to express two polymorphic variant proteins.

13. Furthermore, examining any of inventions XI-XIII together would impose a serious search burden. In the instant case, prior art searches of transgenic animals overexpressing a protein are not coextensive with prior art searches of transgenic

animals that express one or more polymorphic variants of other proteins. Search of each of these inventions would require different key word searches of each compound and of each transgenic animal using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions XI-XIII together.

14. Inventions I-VI are unrelated to inventions XI-XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions I-VI is to delay or reverse a retinal or choridal degenerative disease or condition while the function of the animals of inventions XI-XIII is to express or overexpress a protein.

15. Furthermore, examining any of inventions I-VI together with any of inventions XI-XIII would impose a serious search burden. In the instant case, prior art searches of methods of delaying or reversing a retinal or choridal degenerative disease or condition are not coextensive with prior art searches of transgenic animals that express or overexpress a protein. Search of each of these inventions would require different key word searches of each compound and of each transgenic animal using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious

burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-VI together with any of inventions XI-XIII.

16. Inventions XIV-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of each of inventions XIV-XVIII is to encode a different amino acid sequence.

17. Furthermore, examining any of inventions XIV-XVIII together would impose a serious burden due to the complex nature of the search of nucleotide sequences in terms of computer time needed to perform the search and the subsequent analysis of the search results by the examiner. As such, it would be burdensome to perform examination of any of inventions XIV-XVIII together.

18. Inventions I-VI are unrelated to inventions XIV-XVIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions I-VI is to delay or reverse a retinal or choridal degenerative disease or condition while the function of the sequences of inventions XIv-XVIII is to encode different amino acid sequences.

19. Furthermore, examining any of inventions I-VI together with any of inventions XIV-XVIII would impose a serious search burden. In the instant case, prior art searches

of methods of delaying or reversing a retinal or choridal degenerative disease or condition are not coextensive with computerized nucleotide sequence searches. Search of each of these inventions would require different key word searches of each compound and of each sequence using divergent patent databases, non-patent literature databases and sequence databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-VI together with any of inventions XIV-XVIII.

20. Inventions I-VI are unrelated to inventions XIX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions I-VI is to delay or reverse a retinal or choridal degenerative disease or condition while invention XIX is a gene array.

21. Furthermore, examining any of inventions I-VI together with invention XIX would impose a serious search burden. In the instant case, prior art searches of methods of delaying or reversing a retinal or choridal degenerative disease or condition are not coextensive with prior art searches of a gene array. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious

burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-VI together with invention XIX.

22. Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention VII is to determine the risk of a subject developing a retinal or choridal degenerative disease or condition while the function of invention VIII is to treat a retinal or choridal degenerative disease or condition using a vector that encodes a wild-type or polymorphic variant of an AMDP-related or phagocytosis-related protein.

23. Furthermore, examining inventions VII and VIII together would impose a serious search burden. In the instant case, prior art searches of methods of determining the risk of a subject developing a retinal or choridal degenerative disease or condition are not coextensive with prior art searches of methods of treating a retinal or choridal degenerative disease or condition using a vector that encodes a wild-type or polymorphic variant of an AMDP-related or phagocytosis-related protein. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in

terms of both search and examination. As such, it would be burdensome to perform examination of inventions VII and VIII together.

24. Inventions VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention VII is to determine the risk of a subject developing a retinal or choridal degenerative disease or condition while the function of invention IX is to block expression or activity of an AMDP-related or phagocytosis-related protein.

25. Furthermore, examining inventions VII and IX together would impose a serious search burden. In the instant case, prior art searches of methods of determining the risk of a subject developing a retinal or choridal degenerative disease or condition are not coextensive with prior art searches of compositions of agents that block expression or activity of an AMDP-related or phagocytosis-related protein. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of invention VII together with invention IX.

26. Inventions VII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention VII is to determine the risk of a subject developing a retinal or choridal degenerative disease or condition while the function of invention X is to encode a wild-type or polymorphic form of an AMDP-related or phagocytosis-related protein.

27. Furthermore, examining any of inventions VII and X together would impose a serious search burden. In the instant case, prior art searches of methods of determining the risk of a subject developing a retinal or choridal degenerative disease or condition are not coextensive with prior art searches of vectors that encode a wild-type or polymorphic variant of an AMDP-related or phagocytosis-related protein. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of inventions VII and X together.

28. Invention VII is unrelated to inventions XI-XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention VII is to determine the risk of a subject developing a retinal or

choridal degenerative disease or condition while the function of the animals of inventions XI-XIII is to express or overexpress a protein.

29. Furthermore, examining invention VII together with any of inventions XI-XIII would impose a serious search burden. In the instant case, prior art searches of methods of determining the risk of a subject developing a retinal or choridal degenerative disease or condition are not coextensive with prior art searches of transgenic animals that express or overexpress a protein. Search of each of these inventions would require different key word searches of each compound and of each transgenic animal using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of invention VII together with any of inventions XI-XIII.

30. Invention VII is unrelated to inventions XIV-XVIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention VII is to determine the risk of a subject developing a retinal or choridal degenerative disease or condition while the function of the sequences of inventions XIV-XVIII is to encode different amino acid sequences.

31. Furthermore, examining invention VII together with any of inventions XIV-XVIII would impose a serious search burden. In the instant case, prior art searches of

methods of determining the risk of a subject developing a retinal or choridal degenerative disease or condition are not coextensive with computerized nucleotide sequence searches. Search of each of these inventions would require different key word searches of each compound and of each sequence using divergent patent databases, non-patent literature databases and sequence databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of invention VII together with any of inventions XIV-XVIII.

32. Invention VII is unrelated to invention XIX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention VII is to determine the risk of a subject developing a retinal or choridal degenerative disease or condition while invention XIX is a gene array.

33. Furthermore, examining inventions VII and XIX together would impose a serious search burden. In the instant case, prior art searches of methods of determining the risk of a subject developing a retinal or choridal degenerative disease or condition are not coextensive with prior art searches of a gene array. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious

burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of inventions VII and XIX together.

34. Inventions VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention VIII is to treat a retinal or choridal degenerative disease or condition using a vector that encodes a wild-type or polymorphic variant of an AMDP-related or phagocytosis-related protein while the function of invention IX is to block expression or activity of an AMDP-related or phagocytosis-related protein.

35. Furthermore, examining inventions VIII and IX together would impose a serious search burden. In the instant case, prior art searches of methods of treating a retinal or choridal degenerative disease or condition using a vector that encodes a wild-type or polymorphic variant of an AMDP-related or phagocytosis-related protein are not coextensive with prior art searches of compositions of agents that block expression or activity of an AMDP-related or phagocytosis-related protein. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of invention VIII together with invention IX.

36. Inventions VIII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product could be used to perform a materially different process, for example, a vector that encodes a protein could be used to express the protein in an animal for production of antibodies.

37. Furthermore, examining inventions VIII and X together would impose a serious search burden. In the instant case, prior art searches of methods of treating a retinal or choridal degenerative disease or condition using a vector that encodes a wild-type or polymorphic variant of an AMDP-related or phagocytosis-related protein are not coextensive with prior art searches of compositions of vectors that encode a wild-type or polymorphic variant of an AMDP-related or phagocytosis-related protein. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of invention VIII together with invention X.

38. Invention VIII is unrelated to inventions XI-XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

808.01). In the instant case the different inventions have different functions. The function of invention VIII is to treat a retinal or choridal degenerative disease or condition using a vector that encodes a wild-type or polymorphic variant of an AMDP-related or phagocytosis-related protein while the function of the animals of inventions XI-XIII is to express or overexpress a protein.

39. Furthermore, examining invention VIII together with any of inventions XI-XIII would impose a serious search burden. In the instant case, prior art searches of methods of treating a retinal or choridal degenerative disease or condition using a vector that encodes a wild-type or polymorphic variant of an AMDP-related or phagocytosis-related protein are not coextensive with prior art searches of transgenic animals that express or overexpress a protein. Search of each of these inventions would require different key word searches of each compound and of each transgenic animal using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of invention VIII together with any of inventions XI-XIII.

40. Invention VIII is unrelated to inventions XIV-XVIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention VIII is to treat a retinal or choridal degenerative disease or

condition using a vector that encodes a wild-type or polymorphic variant of an AMDP-related or phagocytosis-related protein while the function of the sequences of inventions XIv-XVIII is to encode different amino acid sequences.

41. Furthermore, examining invention VIII together with any of inventions XIV-XVIII would impose a serious search burden. In the instant case, prior art searches of methods of treating a retinal or choridal degenerative disease or condition using a vector that encodes a wild-type or polymorphic variant of an AMDP-related or phagocytosis-related protein are not coextensive with computerized nucleotide sequence searches. Search of each of these inventions would require different key word searches of each compound and of each sequence using divergent patent databases, non-patent literature databases and sequence databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of invention VIII together with any of inventions XIV-XVIII.

42. Invention VIII is unrelated to invention XIX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention VIII is to treat a retinal or choridal degenerative disease or condition using a vector that encodes a wild-type or polymorphic variant of an AMDP-related or phagocytosis-related protein while invention XIX is a gene array.

43. Furthermore, examining inventions VIII and XIX together would impose a serious search burden. In the instant case, prior art searches of methods of treating a retinal or choridal degenerative disease or condition using a vector that encodes a wild-type or polymorphic variant of an AMDP-related or phagocytosis-related protein are not coextensive with prior art searches of a gene array. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of inventions VIII and XIX together.

44. Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention IX is to block the expression or activity of an AMDP-related or phagocytosis-related protein while the function of invention X is to encode a wild-type or polymorphic form of an AMDP-related or phagocytosis-related protein.

45. Furthermore, examining any of inventions IX and X together would impose a serious search burden. In the instant case, prior art searches of compositions of agents to block the expression or activity of an AMDP-related or phagocytosis-related protein are not coextensive with prior art searches of vectors that encode a wild-type or polymorphic variant of an AMDP-related or phagocytosis-related protein. Search of

each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of inventions IX and X together.

46. Invention IX is unrelated to inventions XI-XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention IX is to block the expression or activity of an AMDP-related or phagocytosis-related protein while the function of the animals of inventions XI-XIII is to express or overexpress a protein.

47. Furthermore, examining invention IX together with any of inventions XI-XIII would impose a serious search burden. In the instant case, prior art searches of compositions of agents to block the expression or activity of an AMDP-related or phagocytosis-related protein are not coextensive with prior art searches of transgenic animals that express or overexpress a protein. Search of each of these inventions would require different key word searches of each compound and of each transgenic animal using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be

burdensome to perform examination of invention IX together with any of inventions XI-XIII.

48. Invention IX is unrelated to inventions XIV-XVIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention IX is to block the expression or activity of an AMDP-related or phagocytosis-related protein while the function of the sequences of inventions XIV-XVIII is to encode different amino acid sequences.

49. Furthermore, examining invention IX together with any of inventions XIV-XVIII would impose a serious search burden. In the instant case, prior art searches of compositions of agents to block the expression or activity of an AMDP-related or phagocytosis-related protein are not coextensive with computerized nucleotide sequence searches. Search of each of these inventions would require different key word searches of each compound and of each sequence using divergent patent databases, non-patent literature databases and sequence databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of invention IX together with any of inventions XIV-XVIII.

50. Invention IX is unrelated to invention XIX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention IX is to block the expression or activity of an AMDP-related or phagocytosis-related protein while invention XIX is a gene array.

51. Furthermore, examining inventions IX and XIX together would impose a serious search burden. In the instant case, prior art searches of compositions of agents to block the expression or activity of an AMDP-related or phagocytosis-related protein are not coextensive with prior art searches of a gene array. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of inventions IX and XIX together.

52. Invention X is unrelated to inventions XI-XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention X is to encode a wild type or polymorphic form of an AMDP-related or phagocytosis-related protein while the function of the animals of inventions XI-XIII is to express or overexpress a protein.

53. Furthermore, examining invention X together with any of inventions XI-XIII would impose a serious search burden. In the instant case, prior art searches of compositions

of vectors that encode a wild type or polymorphic form of an AMDP-related or phagocytosis-related protein are not coextensive with prior art searches of transgenic animals that express or overexpress a protein. Search of each of these inventions would require different key word searches of each compound and of each transgenic animal using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of invention X together with any of inventions XI-XIII.

54. Invention X is unrelated to inventions XIV-XVIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention X is to encodes a wild type or polymorphic form of an AMDP-related or phagocytosis-related protein while the function of the sequences of inventions XIV-XVIII is to encode different amino acid sequences.

55. Furthermore, examining invention X together with any of inventions XIV-XVIII would impose a serious search burden. In the instant case, prior art searches of compositions of vectors that encode a wild type or polymorphic form of an AMDP-related or phagocytosis-related protein are not coextensive with computerized nucleotide sequence searches. Search of each of these inventions would require different key word searches of each compound and of each sequence using divergent

patent databases, non-patent literature databases and sequence databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of invention X together with any of inventions XIV-XVIII.

56. Invention X is unrelated to invention XIX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention X is to encodes a wild type or polymorphic form of an AMDP-related or phagocytosis-related protein while invention XIX is a gene array.

57. Furthermore, examining inventions X and XIX together would impose a serious search burden. In the instant case, prior art searches of compositions of vectors that encode a wild type or polymorphic form of an AMDP-related or phagocytosis-related protein are not coextensive with prior art searches of a gene array. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of inventions X and XIX together.

58. Inventions XI-XIII are unrelated to inventions XIV-XVIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of the animals of inventions XI-XIII is to express or overexpress a protein while the function of the sequences of inventions XIV-XVIII is to encode different amino acid sequences.

59. Furthermore, examining any of inventions XI-XIII together with any of inventions XIV-XVIII would impose a serious search burden. In the instant case, prior art searches of transgenic animals are not coextensive with computerized nucleotide sequence searches. Search of each of these inventions would require different key word searches of each compound and of each sequence using divergent patent databases, non-patent literature databases and sequence databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions XI-XIII together with any of inventions XIV-XVIII.

60. Inventions XI-XIII are unrelated to invention XIX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of the animals of inventions XI-XIII is to express or overexpress a protein while invention XIX is a gene array.

61. Furthermore, examining any of inventions XI-XIII together with invention XIX would impose a serious search burden. In the instant case, prior art searches of transgenic animals are not coextensive with prior art searches of a gene array. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions XI-XIII together with invention XIX.

62. Inventions XIV-XVIII are unrelated to invention XIX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions XIV-XVIII is to encode an amino acid sequence while invention XIX is a gene array.

63. Furthermore, examining any of inventions XIV-XVIII together with invention XIX would impose a serious search burden. In the instant case, prior art searches of nucleotide sequences are not coextensive with prior art searches of a gene array. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and

examination. As such, it would be burdensome to perform examination of any of inventions XIV-XVIII together with invention XIX.

Restriction to a single nucleotide sequence

Required if any of inventions I-VII or XIX is elected

Claims 2, 20, 21, 23 and 50 are subject to an additional restriction since they are each not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1)share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 2, 20, 21 and 50 specifically claim multiple SEQ ID NOS, which are nucleotide sequences of AMDP-related or phagocytosis related genes. Claim 50 recites

additional SEQ ID NOS. Although the sequences claimed are all AMDP-related or phagocytosis related genes, the instant sequences are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct due to their unique nucleotide sequence. As such the Markush/genus of sequences in each of claims 2, 20, 21 and 50 are not considered to constitute a proper genus, and are therefore subject to restriction. Furthermore, a search of more than one (1) of the sequences present in these claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search in terms of computer time needed to perform the search and the subsequent analysis of the search results by the examiner. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) sequence from claim 2. Note that this is not a species election.

Claim 23 specifically claims multiple pairs of SEQ ID NOS, which are amplimers capable of detecting a polymorphism in a region of the human MT1-MMP gene. Although the sequences claimed are all capable of detecting a polymorphism in a region of the human MT1-MMP gene, the instant sequences are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct due to their unique nucleotide sequence. As such the Markush/genus of sequences in claim 23 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one pair of the sequences present in these claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search in terms of computer time needed to perform the search

and the subsequent analysis of the search results by the examiner. In view of the foregoing, one amplimer pair is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one amplimer pair from claim 23. Note that this is not a species election.

If any of inventions I-VI are elected, Applicant must further elect a single sequence from claim 2.

If invention VII is elected, Applicant must further elect a single sequence from those recited in claims 20 and 21 and a single amplimer pair from claim 23.

If invention XIX is elected, Applicant must further elect a single sequence from those recited in claim 50.

Species Election

Required if any of inventions I-VI, XI, XIII or XIX is elected

Claim 9 is generic to a plurality of disclosed patentably distinct species comprising the different cell types recited in this claim. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 37 is generic to a plurality of disclosed patentably distinct species comprising the different cell types recited in this claim. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 42 and 43 are generic to a plurality of disclosed patentably distinct species comprising the different genes recited in these claims. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 52 is generic to a plurality of disclosed patentably distinct species comprising the different genes recited in these claims. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

If any of inventions I-VI are elected, Applicant must further elect a species from claim 9.

If invention XI is elected, Applicant must further elect a species from claim 37.

If invention XIII is elected, Applicant must further elect a species from claim 42 or claim 43.

If invention XIX is elected, Applicant must further elect a species from claim 52.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product

claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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Tracy Vivlemore
Examiner
Art Unit 1635

TV
July 6, 2005

JAMES SCHULTZ
PATENT EXAMINER